

REMARKS

The application has been amended to place the application in condition for allowance at the time of the next Official Action.

The specification is amended to make an editorial change therein.

Claims 1-13 are pending in the application.

Claims 1, 2, 5, 8, 9, and 12 were rejected as anticipated by RENIRIE et al. 6,141,590. That rejection is respectfully traversed.

Independent claims 1 and 8 are amended to clarify that the vagal nerve stimulation (VNS) signal is a central nervous system affecting VNS signal. Accordingly, in the present invention, the central nervous system is stimulated which affects parameters such as respiratory parameters. These parameters are monitored to determine the effect of the stimulation, and the stimulation is regulated in accordance to the response of the parameters. Thus, the parameters are vagal nerve stimulation dependent variables.

The RENIRIE reference is directed to cardiac pacing. As disclosed on column 3, line 67 through column 4, line 10 of RENIRIE, various stimulus signals may be delivered that affect cardiac pacing. However, in each instance, the stimulation provides cardiac rate modulation.

In the method of RENIRIE, the inspiration and expiration phases of a patient are monitored as an independent parameter so that the patient's heart rate may be increased during the phases of inspiration relative to the patient's heart rate during phases of expiration.

RENIRIE does not disclose monitoring respiration as respiration correlates to the VNS intensity.

Rather, as set forth above, RENIRIE monitors respiration as an independent parameter to determine when cardiac pacing should be performed. Thus, the problem solved by RENIRIE is completely different from the problem to be solved by the present invention with respect to central nervous system.

Moreover, as disclosed on page 3, lines 3-10 of the present application, heart effects including heart arrest due to a decrease in heart rate are disadvantages and adverse effects of VNS and have been attributed to inappropriate control of the VNS. Thus, although the heart effects may be attributed to inappropriate control of the VNS, nevertheless VNS is not used to control the heart rate as in RENIRIE.

Accordingly, it is apparent from the above that the method disclosed by RENIRIE is based on cardiac pacing that is not dependent on VNS. RENIRIE does not disclose regulating a VNS intensity in response to at least one parameter (that correlates to the VNS intensity) as recited in claims 1 and 8.

As the reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 3, 8 and 10 were rejected as being anticipated by OBEL et al. 5,199,428. That rejection is respectfully traversed.

Independent claims 1 and 8 are amended to recite a method for adjusting the central nervous system affecting vagal nerve stimulation signal.

By way of example, as disclosed on page 1, lines 13-16 of the present application, the vagal nerve stimulation (VNS) is mediated by the afferent fibers of the vagus nerve, i.e., the stimulation is directed to the central nervous system.

In contrast, OBEL teaches ameliorating myocardial ischemia through vagal nervous stimulation (VNS) to control the heart. OBEL uses parameters such as coronary sinus blood pH or oxygen saturation as indicators of a risk level that is then tried to normalize by the vagal nerve stimulation of the heart. OBEL does not disclose vagal nerve stimulation of the central nervous system. Thus, the problem solved by OBEL is completely different from the one attempted to be solved by the present invention.

Moreover, as set forth above, in known VNS applications which are directed to the central nervous system, the effects

incurred to the heart are adverse effects that should be avoided. See, for example, page 3, lines 3-10.

As the method disclosed by OBEL is directed to VNS applications which are for the heart, OBEL does not anticipate the recited method of adjusting the central nervous system affecting vagal nerve stimulation signal.

Claims 4, 6, 7, 11 and 13 were rejected as unpatentable over RENIRIE. That rejection is respectfully traversed.

Claims 4 and 6 depend from claim 1 and are believed patentable over RENIRIE at least for depending from an allowable independent claim. Claims 11 and 13 depend from claim 8 and are believed patentable over RENIRIE at least for depending from an allowable independent claim as set forth above.

As to independent claim 7, this claim is amended to recite a method for adjusting the central nervous system affecting vagal nerve stimulation (VNS) signal.

As set forth above, RENIRIE is directed to cardiac pacing based on the inspiration and expiration phases of a patient. As set forth above, in the method of RENIRIE, the vagal nerve stimulation does not modulate breathing but instead breathing is an independent parameter which is measured and used for controlling the cardiac pacing. RENIRIE does not disclose regulating the stimulation intensity in response to a respiratory parameter as recited in claim 7.

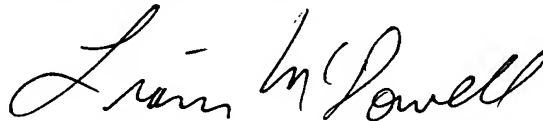
By way of further explanation, neither RENIRIE nor OBEL addresses the problems attempted to be overcome by the present invention. Rather, these references teach away from the present invention by disclosing methods of controlling the heart rate and ignore the adverse effects of vagal nerve stimulation on the heart. Thus, it is apparent that these references neither disclose what is recited nor render obvious the claims of the present invention.

In view of the present amendment and the foregoing remarks, it is believed that the present application has been placed in condition for allowance. Reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



Liam McDowell, Reg. No. 44,231
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

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